

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

SYNGENTA CROP PROTECTION, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
UNITED STATES ENVIRONMENTAL	)	
PROTECTION AGENCY,	)	
	)	
LISA P. JACKSON,	)	
Administrator,	)	
U.S. Environmental Protection Agency,	)	1:02CV00334
	)	
MAKHTESHIM-AGAN OF	)	
NORTH AMERICA, INC.,	)	
	)	
SIPCAM AGRO USA, INC.	)	
	)	
DREXEL CHEMICAL COMPANY, and	)	
	)	
AGAN CHEMICAL	)	
MANUFACTURERS, LTD.	)	
	)	
Defendants.	)	
_____	)	

**MEMORANDUM OPINION**

**I. Procedural Posture**

This case is before the Court on several outstanding motions, all of which will be addressed in this Opinion. The outstanding motions are Sipcam Agro USA, Inc.'s ("Sipcam") Motion for Summary Judgment on Syngenta's Claim of Arbitrary and Capricious Agency Action in Violation of the Administrative Procedure Act [Dock. 308], Drexel Chemical Company's ("Drexel") Motion for Summary

Judgment on Syngenta's Claim of EPA Action in Violation of the Equal Protection Clause and Violation of FIFRA's Exclusive Use Provisions [Dock. 312], United States Environmental Protection Agency's and Lisa P. Jackson's (collectively "EPA") Motion for Summary Judgment [Dock. 316], Makhteshim-Agan of North America, Inc.'s ("MANA"<sup>1</sup>) Motion to Dismiss for Lack of Subject Matter Jurisdiction [Dock. 317], Syngenta Crop Protection, Inc.'s ("Syngenta"<sup>2</sup>) Motion for Summary Judgment [Dock. 319], and MANA's Motion to Unseal MANA's Motion to Dismiss for Lack of Subject Matter Jurisdiction and Memorandum of Law in Support [Dock. 342]. Drexel and Sipcam join MANA's motion to dismiss; Drexel joins Sipcam's motion for summary judgment; and Sipcam joins Drexel's motion for summary judgment. The private Defendants (collectively "Metolachlor Registrants") and EPA present overlapping arguments in their motions and accompanying briefs, while Syngenta's response briefs and own motion and accompanying brief offer related arguments. As a result, all motions can effectively be resolved together in one Opinion. For the following reasons, Sipcam's motion for summary judgment, which Drexel joins, is granted; Drexel's

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<sup>1</sup>MANA is substituted for Cedar Chemical Company. In February 2003, EPA approved the transfer of Cedar's metolachlor registrations and pending applications to MANA. See Syngenta Crop Protection Inc. v. U.S. E.P.A., 222 F.R.D. 271, 277 (M.D.N.C. 2004).

<sup>2</sup>Syngenta is the successor-in-interest to Novartis Crop Protection, Inc. and to Ciba-Geigy Crop Protection, Inc. This Opinion refers to this group's collective interest as "Syngenta."

motion for summary judgment, which Sipcam joins, is granted; EPA's motion for summary judgment is granted; MANA's motion to dismiss, which Sipcam and Drexel join, is granted in part and denied in part; Syngenta's motion for summary judgment is denied; and MANA's motion to unseal is granted.

## **II. Facts**

This Court has previously explained the relevant portions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the background of this case in its previous opinions and will not restate those here except where necessary. See, e.g., Mem. Op., Aug. 8, 2006 [Dock. 249]; Mem. Op., July 12, 2004 [Dock. 126].

Metolachlor was first registered in 1976 for general weed control. Administrative Record [hereinafter "AR"] 7 at 6. In the early 1990's, EPA developed a reduced risk initiative with two basic objectives: (1) to create incentives for the development, registration, and use of lower risk pesticides and (2) to encourage the replacement of higher risk pesticides on the market. AR 3. In the meantime, EPA issued Data Call-Ins (DCIs) to then-current metolachlor registrants, including Syngenta, for the submission of data to maintain the registrations. AR 4-6; see 7 U.S.C. § 136a(c)(2)(B) (explaining EPA's authority to require additional data to maintain registrations). However, the registrants did not submit the required data. AR 211 at 3. Although this resulted in data gaps, EPA did not cancel the metolachlor registrations. Id. In 1995, EPA issued its 37

Reregistration Eligibility Decision (RED) for metolachlor according to which it found that, with few exceptions, most uses of metolachlor would not cause unreasonable risk to humans or the environment. AR 7 at v.

In 1996, under EPA's reduced risk initiative, Syngenta submitted its application for s-metolachlor which used, in part, bridging data from studies submitted for metolachlor's registration. AR 291 at 1; AR11; see also 7 U.S.C. 136a(c)(10) (explaining expedited registration of pesticides). According to the application, s-metolachlor is as effective at weed control as metolachlor when applied at approximately 62.5 percent of the metolachlor rate. AR 291 at 2. As a result, Syngenta believed s-metolachlor would result in reduced environmental loading. Id. However, because metolachlor was then the second most widely used herbicide in the United States, Syngenta was not prepared to cancel its registration immediately in favor of s-metolachlor. Id. at 3. Instead, Syngenta proposed a three- to five-year phase-in period for s-metolachlor. Id.; AR 9. In order to achieve this, Syngenta requested expedited review of s-metolachlor under the reduced risk initiative. AR 291. While EPA was reviewing Syngenta's application for s-metolachlor, EPA's Environmental Fate and Effects Division (EFED) issued comments on s-metolachlor and determined it to be a reduced risk because of the proposed reduction in exposure. AR 9. On March 14, 1997, EPA conditionally

registered s-metolachlor<sup>3</sup> with an expiration date of February 14, 1998. AR 12; AR 211 att. EPA continued its review of data requirements and submissions for s-metolachlor. See, e.g., AR 13 (summarizing EPA's reviews and Syngenta's responses to those reviews).

After EPA registered s-metolachlor conditionally, Syngenta requested voluntary cancellation of all metolachlor registrations on April 11, 1997. AR 113, Vol. 1 at 27; see also 7 U.S.C. 136d(f)(1)(A) (explaining that a registrant may request a voluntary cancellation of a pesticide registration). Syngenta requested that the cancellation of technical metolachlor be effective July 1999, and the cancellation of formulations containing metolachlor to be effective April 2000. AR 113, Vol. 1 at 27. According to Syngenta, EPA requested that Syngenta withdraw its cancellation requests, which it did. Id. at 28.

In January 1998, Syngenta requested that EPA remove the expiration date of s-metolachlor's registration. AR 12.<sup>4</sup> Syngenta recognized the registration would remain conditional, however, due to outstanding data requirements. Id. EPA and Syngenta had remained in communication concerning data requirements for s-

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<sup>3</sup>Not only was S-metolachlor Technical (CGA-77102) registered on March 14, 1997, but so, too, were products containing s-metolachlor. AR 12. These include: Dual MAGNUM Herbicide, Bicep II MAGNUM Herbicide, Dual II MAGNUM Herbicide, Bicep Lite II MAGNUM Herbicide, and Dual II MAGNUM SI Herbicide. Id.

<sup>4</sup>Syngenta understood the expiration date associated with the registration of s-metolachlor to be an oversight by EPA, because, on the same day, EPA registered a pesticide with tolerances that were, themselves, time-limited. AR 12. No such time-limited tolerances relate to s-metolachlor. Id.

metolachlor since its registration in March 1997. AR 13-23. In response to Syngenta's request, EPA "reassessed and found [s-metolachlor] acceptable for conditional registration" without an expiration date. AR 15. As part of s-metolachlor's conditional registration without an expiration date, EPA did require that Syngenta submit certain data, including (1) avian reproduction in bobwhite quail study, (2) aquatic invertebrate life-cycle chronic toxicity study, (3) small-scale prospective ground water monitoring study including terrestrial field dissipation,<sup>5</sup> and (4) fathead minnow life-cycle and early life stage study.<sup>6</sup> Id. EPA determined the bobwhite quail study with metolachlor was not acceptable and could not be bridged. AR 215. EPA found all chronic fish and invertebrate studies with metolachlor to be invalid or supplemental. Id. Thus, they could not be bridged. Id. Most of these studies had been part of the communications between EPA and Syngenta since at least April 1997. See AR 13. In February 1998, EPA's EFED clarified in a memo to the Registration Division which data gaps had to be filled.

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<sup>5</sup>The terrestrial field dissipation study is also referred to as EPA Guideline 164-1. Sipcam Mem. Opp. 2, n. 5 [Dock. 348].

<sup>6</sup>The fathead minnow study is also referred to as EPA Guideline 72-4(a) or Early Life Stage Fish. Id. at 2, n. 4. However, MANA believes the fathead minnow study is the 72-3D guideline study. MANA Mem. Supp. Mtn. Dismiss 10, n. 3 [Dock. 318]. The RED lists 72-4A (there is no 72-4(a)) as Early Life Stage Fish. AR 7 at 75. It lists 72-3D as Estuarine/Marine Toxicity Fish - TEP. Id. EPA required Syngenta to submit a Fathead Minnow Life-Cycle and Early Life Stage Study listed as 72-4(a). AR 15. EPA's EFED also listed the fathead minnow life-cycle and early life stage study as 72-4(a) in its data-gap clarification memo. AR 14. The record supports the labeling of the fathead minnow study as guideline study 72-4(a) or 72-4A, not 72-3D.

AR 14. In listing those data requirements, EFED included additional requirements not mentioned in its original April 1997 data review. Id. EPA and Syngenta continued to debate data requirements for s-metolachlor at least through January 1999. AR 16-23.

Syngenta resubmitted its request for voluntary cancellation of metolachlor in September 1999. AR 113, Vol. 1 at 28 (suggesting Syngenta sought cancellation of technical and end-use metolachlor); AR 293 (requesting cancellation of Metolachlor Technical). In December 1999, EPA published notice in the Federal Register of the receipt of Syngenta's request to cancel its metolachlor registrations. AR 294; see also 7 U.S.C. § 136d(f)(1)(B), (C) (explaining that EPA must publish in the Federal Register for 180 days notice of its receipt of a request for voluntary cancellation of a pesticide registered for minor agricultural uses and the termination of which would adversely affect its availability). In addition, Syngenta ceased paying maintenance fees for its technical and end-use registrations. See AR 295 (informing Syngenta in February 2000 of EPA's intent to cancel Syngenta's registrations due to failure to pay maintenance fees); AR 301 (informing Syngenta in February 2001 of EPA's intent to cancel Syngenta's registrations due to failure to pay maintenance fees).

Shortly after publication, in January 2000, then-Cedar Chemical Corporation ("Cedar") applied for a me-too registration of Metolachlor Technical dependent upon Syngenta's metolachlor registrations. See AR 29; see also 7 U.S.C. §

136a(c)(7)(A) (describing conditional registration of a pesticide or proposed use that is identical or substantially similar to any currently registered pesticide or use thereof and which would not significantly increase the risk of any unreasonably adverse effect on the environment). In response, in March 2000, Syngenta petitioned EPA to deny Cedar's application. AR 25. However, neither Cedar nor Syngenta provided EPA with sufficient information to determine the relative risk of s-metolachlor compared with Metolachlor Technical. AR 52. As a result, EPA requested that both parties submit further data to assist EPA in its determination. Id.

During the period for public comment regarding Syngenta's voluntary cancellation, in June 2000, Cedar submitted objections to the cancellation of Syngenta's products, in part due to Cedar's pending me-too application for Metolachlor Technical. AR 297. Although the public comment period ended in June 2000, EPA did not issue a cancellation order immediately thereafter.

Sipcam applied in October 2000 for a me-too Metolachlor Technical conditional registration dependent, like Cedar's application, on Syngenta's metolachlor registrations. AR 217.<sup>7</sup> Just as it had for Cedar's application, Syngenta filed in November 2000 a petition to deny Sipcam's application. AR 222.

In April 2001, Cedar ultimately submitted a revised application for its me-too

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<sup>7</sup>AR 217 is a sealed document; however, Syngenta acquired the same document through the Freedom of Information Act. See Dock. 322, Ex. 3. Thus, the information contained therein is not sealed within this Opinion.



technical metolachlor registration and two applications for me-too end-use registrations.<sup>8</sup> AR 55-57. In response, Syngenta petitioned to deny Cedar's revised technical metolachlor application.<sup>9</sup> AR 82.

EPA eventually cancelled Syngenta's end-use metolachlor registrations in July 2001. 66 Fed. Reg. 38675, 38682 (noting the cancellation of, among others, Dual 8E Herbicide and Dual II Herbicide, for non-payment of maintenance fee). However, EPA left in effect Syngenta's Metolachlor Technical registration until EPA had reviewed the me-too applications. AR 303; AR 304.

Drexel followed Cedar and Sipcam and applied in September 2001 for a me-too Metolachlor Technical registration. AR 263.<sup>10</sup> Thereafter, in December 2001, Syngenta petitioned EPA to deny Drexel's application. AR 266, 269.

Despite Syngenta's petitions to deny the me-too applications, EPA issued Cedar's me-too conditional Metolachlor Technical and end-use registrations March 2002. AR 208-210. In so doing, EPA's Herbicide Branch drafted a memorandum reviewing the unreasonable adverse effect standard and data requirements for the

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<sup>8</sup>Cedar's me-too applications were for Technical Metolachlor II, INTER Plus II, and INTER 8E II.

<sup>9</sup>The Court is unable to find in the Administrative Record evidence that Syngenta petitioned EPA to deny Cedar's end-use applications.

<sup>10</sup>The Administrative Record on file with the Court identifies AR 263 as having been redacted from the record. However, Syngenta freely cites AR 263 as Exhibit 4 to Docket 322. Therefore, information from AR 263 is not sealed within this Opinion.

me-too registrations. AR 211. This document also “constitute[d]” EPA’s decision concerning Syngenta’s petition to deny Cedar’s applications. Id. In April 2002, EPA issued Sipcam’s and Drexel’s technical me-too registrations. AR 261; AR 289. Just as it had in anticipation of registering Cedar’s me-too pesticides, EPA drafted an explanation of its decision which cited the Herbicide Branch’s earlier memorandum to Cedar. AR 262; AR 290.

EPA conditioned these registrations on the submission of six studies that remained data gaps from the previously issued DCIs for metolachlor: (1) avian reproduction in bobwhite quail 71-4(a), (2) aquatic invertebrate life-cycle 72-4(b), (3) turf field dissipation 164-1, (4) foliar residue dissipation 132-1(a), (5) dermal passive dosimetry exposure 133-3, and (6) small scale prospective ground water monitoring 166-1. AR 208; AR 261; AR 289. Since the data submission deadlines for the DCIs had passed, EPA extended the deadlines for Cedar, Sipcam, and Drexel to submit the required data. AR 208; AR 261; AR 289.

Once EPA registered Cedar’s, Sipcam’s, and Drexel’s me-too pesticides, EPA determined “the purpose of FIFRA § 6(f) procedures ha[d] been served,” and it was “prepared to act on Syngenta’s request for voluntary cancellation.” AR 304. However, EPA provided Syngenta the opportunity to withdraw its voluntary cancellation request if it chose “to have continued access to the metolachlor market.” Id. Syngenta did not withdraw its cancellation request, and EPA cancelled Syngenta’s technical metolachlor registration in August 2002. Dock.

### **III. Threshold Issues**

In its motion to dismiss for lack of subject matter jurisdiction, MANA contends (1) the case is moot, (2) the Court lacks jurisdiction to address Count II because Syngenta erroneously brought it under the Administrative Procedure Act (APA), (3) Syngenta lacks standing to pursue any of the three counts in its complaint, and (4) Syngenta's unclean hands bar its receipt of equitable relief. EPA also argues Syngenta lacks standing to pursue its claims. Upon review, it is determined that the Court does not have sufficient information to determine that the case is moot; the Court does have jurisdiction to hear Count II; Syngenta has standing to pursue Count I, Count III, and portions of its claims in Count II; and the Court will not exercise its discretion to apply the unclean hands doctrine.

#### **A. Mootness**

MANA argues that events transpiring after Syngenta filed its Second Amended and Supplemental Complaint (SASC) [Dock. 265] render Syngenta's allegations moot. Because "[t]he doctrine of mootness constitutes a part of the constitutional limits of federal court jurisdiction," "'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.'" Brooks v. Vassar, 462 F.3d 341, 348 (4th Cir. 2006) (quoting Arizonans for Official English v. Arizona, 520 U.S. 43, 67 (1997)). "[I]f a party can demonstrate that the apparent absence of a live dispute is merely a temporary abeyance of a harm that is 'capable of repetition, yet evading review,'" the case is not moot. Id.

Here, as MANA correctly notes, Syngenta stated in its Memorandum in Opposition to MANA's Motion to Compel that

even had EPA cancelled Syngenta's metolachlor registrations as it should have done, the private defendants could have obtained unconditional metolachlor applications under FIFRA § 3(c)(5), notwithstanding the cancellations, if they had applied in the years earlier or simply cited Syngenta's metolachlor database, . . . and undertaken a small handful of studies required to complete the scientific database for metolachlor before submitting their applications.

Syngenta's Mem. Opp. MANA's Mtn. Compel 14. The studies necessary to fill the metolachlor data gaps included avian reproduction in bobwhite quail, life cycle chronic toxicity in mysid shrimp, early life stage chronic toxicity in fathead minnows, small scale prospective groundwater study including a terrestrial field/foliar residue dissipation component, and a turf dissipation study. SASC ¶ 128. The Metolachlor Registrants' registrations were conditioned on the submission of each of these studies except the fathead minnow study.<sup>11</sup> AR 208-210. However, in August 2002, Drexel and Sipcam notified EPA that they were removing turf use from their technical metolachlor labels. Dock. 318, Ex. 11. After publication of the use deletions and time for public comment, EPA was to delete

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<sup>11</sup>MANA explains that EPA did not require the fathead minnow study because EPA determined as part of the RED that the study was not applicable. MANA cites guideline study 72-3D in the RED as being "N/A," see AR 7 at 75; however, as explained supra in footnote 6, the fathead minnow study is guideline study 72-4(a) or 72-4A. The RED provides a citation for the 72-4A study, indicating no data gap for metolachlor. AR 7 at 75. This is the more likely explanation for its not appearing on the Metolachlor Registrants' conditional registration requirements.

officially turf use from their labels. Id. Then, the turf field dissipation and foliar residue dissipation studies would no longer be required. Id. In July 2005, MANA<sup>12</sup> sought a similar cancellation of turf uses from its technical metolachlor registration. Id. As a result, of the studies initially required of the Metolachlor Registrants, only the bobwhite quail, mysid shrimp, and groundwater study without the dissipation component remain required studies. According to MANA, the Metolachlor Registrants have submitted these studies to EPA and requested unconditional registration under 7 U.S.C. 136a(c)(5). Dock. 318, Ex. 12. Although MANA describes EPA's pending action as "ministerial," see MANA's Mem. Supp. Mtn. Dismiss 11, neither MANA, nor any other Metolachlor Registrant, has submitted evidence to the Court that EPA has granted the Metolachlor Registrants unconditional registrations. Thus, there is insufficient evidence to determine Syngenta's claims are moot.

MANA also argues Syngenta's claims are moot because, even if Syngenta's studies were entitled to exclusive use protections at the time EPA granted the me-too registrations, they are no longer exclusive use studies. MANA correctly calculates that, according to the record, Syngenta's studies would presently not be exclusive use studies. However, evidence in the record supports Syngenta's contention, for purposes of MANA's mootness argument, that Syngenta's studies were entitled to exclusive use protection at the time EPA issued me-too

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<sup>12</sup>Cedar transferred its registrations to MANA in 2003.

registrations to the Metolachlor Registrants. The expiration of such protection due to the passage of time does not make Syngenta's claims of exclusive use right violations moot.

## **B. Jurisdiction to Hear Count II**

The APA "provides a framework for judicial review of final agency action when an adequate remedy is otherwise lacking." Defenders of Wildlife v. Admin., E.P.A., 882 F.2d 1294, 1303 (8th Cir. 1989) (analyzing the relationship between the APA and FIFRA) (citing 5 U.S.C. § 704). This is not such a case. Instead, "FIFRA provides for judicial review of the EPA's pesticide registration decisions." Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv., 637 F.3d 259, 262 (4th Cir. 2011) (citing 7 U.S.C. § 136n). While FIFRA provides for judicial review, the APA provides the scope of such review. Defenders of Wildlife, 882 F.2d at 1303 (citing 5 U.S.C. § 706).

Syngenta entitled Count II "Arbitrary and Capricious Agency Action in Violation of the APA." Although this title is inartful in its suggestion that a violation of the APA is sufficient for judicial review in this case, Syngenta asserts that it "is not attempting to make a collateral attack on EPA's actions under FIFRA by invoking the APA." Syngenta Mem. Opp. MANA's Mtn. Dismiss 15 [Dock. 358]. Syngenta not only acknowledges that FIFRA provides for judicial review of agency action under the statute, but it contends its claims in Count II are violations of FIFRA reviewable under the APA standard of review. Id. at 14-15. In reviewing

Count II and Syngenta's understanding of the law, it is determined that Syngenta's allegations in Count II are brought as violations of FIFRA, not the APA. Therefore, the Court does have jurisdiction to hear Count II.

### **C. Standing**

"The standing doctrine is an indispensable expression of the Constitution's limitation on Article III courts' power to adjudicate 'cases and controversies.'" Frank Krasner Enters., Ltd. v. Montgomery County, MD, 401 F.3d 230, 234 (4th Cir. 2005) (quoting Allen v. Wright, 468 U.S. 737, 750-51 (1984)). The standing analysis involves "constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise." Warth v. Seldin, 422 U.S. 490, 498 (1975). "[T]he question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues,' which is always a distinct inquiry from the question of how a litigant's claim should be decided." Long Term Care Partners, LLC v. United States, 516 F.3d 225, 241 (4th Cir. 2008) (quoting Warth, 422 U.S. at 498). Standing "does not depend upon [a plaintiff's] ultimate success on the merits underlying his case." Covenant Media of SC, LLC v. City of North Charleston, 493 F.3d 421, 429 (4th Cir. 1007) (citing Warth, 422 U.S. at 500).

It is the burden of the plaintiff to support each element of standing "in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of

the litigation.” Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992).

Therefore, in response to a motion for summary judgment, the plaintiff must cite to particular parts of materials in the record. Lujan, 504 U.S. at 561 (citing earlier version of Fed. R. Civ. P. 56(e)). Furthermore, the plaintiff must establish standing for each claim it asserts. DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006) (citing Allen, 468 U.S. at 752).

The “irreducible constitutional minimum of standing” requires (1) that the plaintiff have suffered an injury in fact, (2) that there be a causal connection between the injury and the conduct challenged, and (3) that a favorable decision will redress the injury. Lujan, 504 U.S. at 560-61. The plaintiff’s injury in fact must be an invasion of a legally protected interest which is concrete, particularized, and actual or imminent. Id. at 560. The causal connection demands the plaintiff’s injury be “‘fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court.’” Id. (quoting Simon v. E. Ky. Welfare Rts. Org., 426 U.S. 26, 41, 42 (1976)). Finally, it must be “likely,” not merely speculative, that a favorable ruling will redress plaintiff’s injury. Id. (quoting Simon, 426 U.S. at 38, 43). If the plaintiff is an object of the challenged action or inaction, “there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.” Id. at 561-62. On the other hand, standing becomes “substantially more difficult” to prove when the plaintiff’s



injury results from unlawful government regulation of someone else. Id. at 562.

Prudential standing often involves matters of judicial self-governance that protect courts from having to “decide abstract questions of wide public significance even though other governmental institutions may be more competent to address the questions and even though judicial intervention may be unnecessary to protect individual rights.” Warth, 422 U.S. at 500. Prudential considerations include “the requirement that a plaintiff’s complaint fall within the zone of interests protected by the law invoked” and the general prohibitions on a plaintiff raising a third party’s rights and the adjudication of general grievances. Allen, 468 U.S. at 751; see also Ass’n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 153 (1970) (“[T]he question [is] whether the interest sought to be protected by the complainant is arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.”). In determining whether the plaintiff’s interests fall within those arguably to be protected, the “inquiry must be determined not by reference to the overall purpose of the statute in question but, instead, by reference to the particular provision(s) of law upon which the plaintiff seeks redress.” Taubman Realty Grp. Ltd. P’ship v. Mineta, 320 F.3d 475, 480 (4th Cir. 2003) (internal citations omitted).

In order for a plaintiff’s interests to be within the zone of interests *regulated* by the statute in question, the plaintiff must be directly regulated by the agency action it challenges. Calumet Indus., Inc. v. Brock, 807 F.2d 225, 228-29 (D.C.

Cir. 1986). “It is not enough that [a plaintiff] be regulated merely by the statute upon which the agency action is based.” Id.; cf. Taubman Realty Grp. Ltd. P’ship, 320 F.3d at 480 (stating the relevant focus is on the particular provision of the law upon which the plaintiff seeks redress).

In order for a plaintiff that is not the subject of the contested regulatory action to have prudential standing, its interests cannot be “so marginally related to or inconsistent with the purposes implicit in the statute.” TAP Pharm. v. U.S. Dep’t of Health & Hum. Servs., 163 F.3d 199, 203 (4th Cir. 1998) (quoting Clarke v. Sec. Indus. Ass’n, 479 U.S. 388, 399 (1987)). Therefore, to determine whether plaintiff’s interests are within the zone of interests to be *protected*, the court must “first discern the interests ‘arguably . . . to be protected’ by the statutory provision at issue” and “then inquire whether the plaintiff’s interests affected by the agency action in question are among them.” Id. (quoting Nat’l Credit Union Admin. v. First Nat’l Bank & Trust Co., 522 U.S. 479, 492 (1998)). The statute’s language and legislative history are relevant to determining what interests the statutory provision arguably protects. Blackhawk Indus. Prods. Grp. Unltd., LLC v. U.S. Gen. Servs. Admin., 348 F.Supp.2d 662, 671 (E.D.Va. 2004) (citing Air Courier Conf. of Am. v. Am. Postal Workers Union AFL-CIO, 498 U.S. 517 (1991)). When a plaintiff asserts its commercial interests, those interests are within the zone of interest only if those interests “put [the plaintiff] in the same position as a member of the [group subject to the statutory provision] or a commercial competitor of such a member.”

TAP Pharm., 163 F.3d at 208. The Fourth Circuit has recognized that

[t]he Supreme Court rulings providing commercial competitors with standing reflect the principle that when Congress passes a statute regulating a defined class, its intention to limit the class must be given the same respect as its intention to regulate it. . . . Where . . . commercial interests are concerned, this legislative restraint can be presumed to indicate a Congressional intention to protect the interests of the competitors of the parties regulated from encroachment beyond that caused by the statute's terms. Such a presumption can safely be made because, in the commercial sphere, benefit or detriment to one party can be fairly assumed to have the opposite effect on the interests of the party's competitors.

Id. at 207-08.

### **1. Count I**

In Count I of the SASC, Syngenta asserts a violation of the exclusive use protection provisions in FIFRA. Specifically, Syngenta alleges that it has a proprietary right to the ten-year exclusive use of studies that it submitted in 1998 to EPA in support of its application to register s-metolachlor. SASC ¶ 175. Syngenta alleges that, in issuing metolachlor registrations to the Metolachlor Registrants, EPA relied on Syngenta's chronic toxicity study on fathead minnows and terrestrial field dissipation study. Id. at ¶ 177. Syngenta further alleges that EPA failed to provide Syngenta, the original data submitter, with the requisite thirty days notice and opportunity to obtain information on the Metolachlor Registrants' applications. Id. at ¶¶ 178-80. Not only has Syngenta alleged injury in fact in its complaint, but it has, as it must at this stage, supported its allegations with facts

in the Administrative Record.<sup>13</sup>

As part of its registration of s-metolachlor, Syngenta submitted studies, including: (1) avian reproduction in bobwhite quail, (2) aquatic invertebrate life-cycle chronic toxicity, (3) early life stage chronic toxicity in fathead minnows, and (4) small scale prospective ground water monitoring, including a terrestrial field dissipation study. AR 15. Ten-year exclusive use protection is afforded to studies that (1) pertain to a new active ingredient/chemical first registered after September 30, 1978, (2) were submitted in support of or as a condition of the application resulting in the first application of a product with the new active ingredient/chemical or an application to amend such registration to add a new use, and (3) were not submitted to satisfy FIFRA § 3(c)(2)(B), which requires data to maintain a registration. 40 C.F.R. § 152.83.

Syngenta contends its studies submitted in support of s-metolachlor's registration meet the requirements as exclusive use studies. Syngenta applied to register s-metolachlor under the reduced risk initiative's expedited review process. AR 291. As part of its application, Syngenta used bridging data from metolachlor's registration. Id. EPA conditionally registered s-metolachlor on March 14, 1997 with an expiration date of February 14, 1998. AR 211, att.; AR 15. During its continued review of data requirements and submissions for s-

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<sup>13</sup>At this stage in the Opinion, Syngenta's allegations and facts in the AR are used solely to determine the issue of standing. The merits of Syngenta's claims are addressed later in the Opinion.

metolachlor, EPA determined Syngenta needed to submit additional studies particular to s-metolachlor. AR 14-23. Syngenta agreed to submit certain studies, but contested the necessity of others. See, e.g., AR 13.

In January 1998, Syngenta requested removal of the expiration date to which EPA agreed as long as Syngenta submitted various studies. AR 15. These studies had been part of the discussion between EPA and Syngenta since s-metolachlor's conditional registration. AR 13 (summarizing EPA's reviews and Syngenta's responses). EPA acknowledged that it had "reassessed" s-metolachlor and "found [it] acceptable for conditional registration" as long as the listed studies were submitted by particular dates. AR 15. Subsequently, Syngenta submitted requested studies. See, e.g., AR 23.

According to Syngenta, not only were its studies entitled to exclusive use protection, but EPA allegedly violated Syngenta's exclusive use protection. Syngenta argues EPA did so by permitting the Metolachlor Registrants to use Syngenta's fathead minnow and terrestrial field dissipation studies to support their me-too metolachlor registrations. In assessing data requirements for s-metolachlor, EPA determined the existing fathead minnow study for metolachlor to be supplemental. AR 14. In addition, EPA listed the terrestrial field dissipation study as part of the 164-1 dissipation studies that remained data gaps from EPA's review of s-metolachlor in April 1997. AR 15. Therefore, EPA required Syngenta to submit these studies as part of s-metolachlor's registration. AR 15. However, EPA

did not require the Metolachlor Registrants to submit those studies in support of their me-too registrations. AR 208; AR 261; AR 289. Syngenta reasons that if it had to submit the studies according to EPA's explanations, so, too, should the Metolachlor Registrants. Since EPA did not require the Metolachlor Registrants to submit either study, Syngenta concludes EPA must have relied on Syngenta's fathead minnow study and terrestrial field dissipation study to support the me-too registrations. If EPA did so, as Syngenta alleges, EPA violated Syngenta's exclusive use rights to those studies.

Syngenta also alleges EPA failed to provide it thirty days notice before registering "a product containing an active ingredient for which a previously submitted study is eligible for exclusive use." 40 C.F.R. § 152.116(a). If the exclusive use data submitter requests within thirty days of the notice, EPA must provide the applicant's data requirements and method of demonstrating compliance with the requirements. Id. According to Syngenta, EPA failed to do so. See AR 25 at 30; AR 82 at 45.

Without determining Syngenta's claim on its merits, the Court finds Syngenta has supported its allegations of injury in fact with evidence from the record<sup>14</sup> that describe an injury in fact. The same facts from the record also suggest the injury is fairly traceable to the actions of EPA.

Finally, a favorable decision by this Court would redress the injury. Among

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<sup>14</sup>See supra pp. 20-22.

the relief Syngenta seeks are its requests that the Court order the Metolachlor Registrants' me-too registrations cancelled and, at the request of the Metolachlor Registrants, remand to EPA to allow it to evaluate properly the me-too registrations as the Metolachlor Registrants may revise them. SASC at 47, ¶ 13. Further, Syngenta requests this Court to enjoin the Metolachlor Registrants from manufacturing, distributing, or selling metolachlor, using any metolachlor registration, or transferring any metolachlor registration. Id. at ¶ 14. If the Court were to grant Syngenta any of these requests for relief, the Metolachlor Registrants would effectively be unable to continue to benefit from the me-too registrations at issue in this case that EPA allegedly registered using Syngenta's exclusive use studies. Although Syngenta's studies submitted for s-metolachlor in 1998 would likely not be exclusive use studies presently,<sup>15</sup> they would have been exclusive use studies, if at all, at the time the me-too registrations were issued. Thus, if the me-too registrations were issued using Syngenta's exclusive use studies, not only were they unlawfully issued, but any subsequent registrations based on the me-too registrations at issue would likely also be unlawful. Cancelling those registrations and, at the request of the Metolachlor Registrants, remanding to EPA and permitting the Metolachlor Registrants to revise their

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<sup>15</sup> Exclusive use studies are protected for ten years. 7 U.S.C. § 136a(c)(1)(F)(I). However, in certain instances, the period of exclusive use can be extended. 7 U.S.C. § 136a(c)(1)(F)(ii). It is unclear whether Syngenta's studies would have received an extended period of protection.

metolachlor applications would protect Syngenta from any further injury.

Not only has Syngenta established constitutional standing regarding Count 1, but it also has prudential standing to bring the claim. Exclusive use protection is “primarily concerned with protecting the economic interests of data submitters.” 49 Fed. Reg. 30884, 30888. Its purpose is to “encourage continued research and development of new, more effective, and safer pesticides by giving producers — who often devote many years and millions of dollars to developing a new pesticide — a period of protection against competition.” Id. If Syngenta’s studies submitted for s-metolachlor are exclusive use studies, Syngenta is certainly within the zone of interests of 7 U.S.C. 136a(c)(1)(F) and 40 C.F.R. § 152.83. Syngenta has, therefore, cited to evidence in the Administrative Record that supports the determination that Syngenta is in the proper position so as to make the argument that its exclusive use rights were violated and to pursue such a claim.

## **2. Count II**

Syngenta’s standing to pursue Count I does not confer standing for the remaining counts. Syngenta must establish standing for each claim it asserts. In Count II of the SASC, Syngenta broadly alleges arbitrary and capricious agency action in violation of the APA. However, the allegations in Count II are varied and, at times, redundant. Thus, the Court analyzes each paragraph of Count II that asserts a claim to determine whether Syngenta has standing to pursue that particular claim. After doing so, it is determined that Syngenta has standing to



challenge the actions asserted in paragraph 188. While Syngenta meets the standing requirements for the allegation in paragraphs 184, the assertion is duplicative of those made in paragraphs 178 and 179 of Count I. Likewise, although Syngenta has standing to pursue the allegations in paragraphs 189 and 193 that relate to EPA's registering the Metolachlor Registrants' pesticides under 7 U.S.C. § 136a(c)(7)(A) when Syngenta had requested that EPA cancel its registrations, these assertions reiterate the allegation in paragraph 188 of Count II.

In paragraph 184, Syngenta alleges "EPA's failure, in violation of FIFRA and its implementing regulations, to provide Syngenta with thirty days notice prior to issuing the metolachlor registrations, and the opportunity to obtain additional information regarding any support that exists for the registrations, is arbitrary and capricious." This allegation mirrors those in paragraph 178, 179, and 180 of Count I. See supra p. 22. As such, although Syngenta meets the standing requirements to pursue the allegation in paragraph 184, see supra pp. 20-24, the paragraph is duplicative of Syngenta's contentions in Count I.

Syngenta's allegations in paragraphs 185, 186, and 187 are not stand alone claims, nor may they be integrated in Syngenta's allegations in Count 1 because Syngenta lacks standing to assert them. In paragraphs 185, 186, and 187, Syngenta presents very similar, if not the same, allegations. In paragraph 185, Syngenta asserts that EPA's refusal to provide a reasoned basis for its decision to deny Syngenta's petitions to deny was arbitrary and capricious. Similarly, in

paragraph 186, Syngenta contends EPA's March 21, 2002 memorandum did not explain EPA's decision to grant the Metolachlor Registrants' registrations and failed to address the issues Syngenta raised in its petitions to deny. Consequently, according to Syngenta, these actions were also arbitrary and capricious. In paragraph 187, Syngenta merely reiterates its argument that EPA de facto denied Syngenta's petitions to deny and states the standard of review of such actions under the APA. All three paragraphs assert the same claim — EPA's failure to provide a reasoned explanation for its denial of Syngenta's petitions to deny and grant of the Metolachlor Registrants' registrations was arbitrary and capricious. If, as Syngenta contends, its studies submitted in support of s-metolachlor are exclusive use studies, then Syngenta would have been able to "petition [EPA] to deny . . . the registration of a product . . . [since Syngenta] has submitted to [EPA] a valid study which, [Syngenta] claims, satisfies a data requirement that an applicant purportedly has failed to satisfy." 40 C.F.R. § 152.99. Under the impression that it held exclusive use rights to the studies in question, Syngenta petitioned EPA to deny the Metolachlor Registrants' registrations. AR 25; AR 222; AR 82; AR 266; AR 269. Although Syngenta alleges EPA's response to the petitions was arbitrary and capricious, Syngenta alleges no injury in fact. If its exclusive use rights allegations are correct and it, therefore, had the right to petition EPA to deny a registration pursuant to 40 C.F.R. § 152.99, Syngenta was not prevented from doing so. Consequently, Syngenta does not have standing to

pursue its allegations in paragraphs 185, 186, and 187.

In paragraph 188, Syngenta contends EPA's refusal to cancel Syngenta's technical metolachlor registration until EPA had evaluated the Metolachlor Registrants' applications was arbitrary and capricious, not in accordance with the law, and, thereby, singled out Syngenta for treatment that differed from all other similarly-situated parties. As 7 U.S.C. § 136d(f)(1)(A) permits, in September 1999, Syngenta submitted its request for voluntary cancellation of metolachlor, including technical metolachlor. AR 293. As required, EPA published notice of Syngenta's cancellation request in the Federal Register in December 1999. AR 294. Syngenta also ceased paying maintenance fees for its technical metolachlor. AR 295; AR 301. However, EPA did not cancel Syngenta's technical metolachlor until August 2002. Dock. 330, Ex. 3.

After Syngenta sought voluntary cancellation and EPA published notice of the request, Cedar, Sipcam, and Drexel applied for me-too registrations dependent on Syngenta's metolachlor registrations. AR 29; AR 217; AR 263. As a result, EPA delayed cancelling Syngenta's technical metolachlor while EPA reviewed applications for technical me-too registrations. AR 303; AR 304. EPA would not have been able to grant the me-too registrations without a substantially similar or identical pesticide currently registered. 7 U.S.C. § 136a(c)(7)(A). Prior to its cancellation of Syngenta's technical metolachlor registration, EPA issued me-too registrations to Cedar, Sipcam, and Drexel. AR 208; AR 261; AR 289. By

delaying the cancellation of Syngenta's technical metolachlor registration, EPA permitted Cedar, Sipcam, and Drexel to obtain me-too registrations based on Syngenta's technical metolachlor registration.

Cedar, Sipcam, and Drexel obtained registration under 7 U.S.C. § 136a(c)(7)(A). However, had Syngenta's technical metolachlor been cancelled after EPA complied with the procedures set forth in 7 U.S.C. § 136d(f)(1)(A)-(C) by providing notice and time for public comment, Cedar, Sipcam, and Drexel would likely have had to register under the 7 U.S.C. § 136a(c)(7)(C) or 7 U.S.C. § 136a(c)(5) more stringent registration provisions. Instead, Syngenta's metolachlor registrations were used by EPA to provide a me-too basis for Cedar's, Sipcam's, and Drexel's registrations despite Syngenta's request to cancel its registrations. As a result, Cedar, Sipcam, and Drexel became competitors of Syngenta in the technical metolachlor market. If EPA's actions were improper, not only did Syngenta suffer a competitive or commercial injury, but EPA's actions clearly caused the injury which a favorable court decision would redress. Among Syngenta's requests for relief is the request that the me-too registrations be cancelled and, if the Metolachlor Registrants choose, revised and reassessed by EPA. As a result, Cedar, Sipcam, and Drexel would likely have to submit applications no longer based on Syngenta's now-cancelled registrations.

Not only does Syngenta meet the constitutional requirements for standing to pursue the claim in paragraph 188, but Syngenta also meets the prudential

requirements. Syngenta is directly regulated by the agency action - or delayed action - it challenges. Syngenta sought voluntary cancellation pursuant to 7 U.S.C. § 136d(f)(1), and EPA delayed such cancellation in order to review and register metolachlor applications submitted after public notice of Syngenta's cancellation request. As the subject of the contested regulatory action, Syngenta is within the zone of interests regulated by the statutory provision in question. Thus, Syngenta has cited to evidence in the Administrative Record that supports the determination that Syngenta is in the proper position to make the argument that EPA's delay in cancelling Syngenta's metolachlor registrations was arbitrary and capricious and to pursue such a claim.

Although Syngenta does have standing to challenge EPA's actions alleged in paragraph 188 as arbitrary and capricious, Syngenta's assertion that EPA's actions "singled out Syngenta for treatment that differed from all other similarly-situated parties" is an equal protection claim, not a claim of arbitrary and capricious agency action.

Paragraphs 189 and 193 seem to allege the same violation and are treated as asserting the same claim for purposes of the standing analysis. Paragraph 189 alleges "EPA acted arbitrarily and capriciously, in violation of FIFRA, in granting metolachlor registrations . . . under FIFRA § 3(c)(7)(A) rather than FIFRA § 3(c)(7)(C)." Similarly, in paragraph 193, Syngenta contends "EPA acted arbitrarily and capriciously . . . in evaluating the Metolachlor Registrants' applications under

FIFRA § 3(c)(7)(A), because the products proposed for registrations were not identical or substantially similar in composition and proposed use to any pesticide product then currently registered.” It is unclear both from the SASC and Syngenta’s briefs on what basis it is challenging EPA’s actions. Syngenta seems to be arguing either (1) EPA relied on Syngenta’s registrations for which it was seeking voluntary cancellation when EPA analyzed and registered the me-too pesticides or (2) EPA registered Cedar’s two end-use me-too pesticides after EPA had cancelled Syngenta’s end-use registration or (3) both. Compare Syngenta Mtn. S.J. 3, ¶ 9 [Dock. 319] (stating that because Syngenta’s technical registration was effectively cancelled, EPA was required to analyze and register the Metolachlor Registrants’ applications under FIFRA § 3(c)(5) or FIFRA § 3(c)(7)(C)), with Syngenta Mem. Supp. Mtn. S.J. 7 [Dock. 320] (stating EPA violated FIFRA by issuing Cedar’s two end-use registrations after EPA cancelled Syngenta’s end-use registration), and Syngenta Mem. Opp. Sipcam’s Mtn. S.J. 4-8 [Dock. 346] (distinguishing technical and end-use metolachlor and arguing applications for end-use metolachlor must be compared to existing end-use, not technical, metolachlor).

This Court found in its March 31, 2006 Memorandum Opinion that EPA’s determination of the substantial similarity of the Metolachlor Registrants’ pesticides to Syngenta’s pesticides was committed to the Agency’s discretion and, thus, not reviewable. Syngenta Crop Prot., Inc. v. U.S. EPA, 439 F.Supp.2d 458, 463 (M.D.N.C. 2006). In its Memorandum in Opposition to Sipcam’s Motion for

Summary Judgment, Syngenta essentially argues technical metolachlor is not substantially similar to end-use metolachlor, and, consequently, EPA improperly found the two to be substantially similar when it registered the me-too end-use pesticides. Syngenta Mem. Opp. Sipcam's Mtn. S.J. 4-8. These allegations are not reviewable.

However, in so far as Syngenta alleges in paragraphs 189 and 193 that EPA's actions are arbitrary and capricious because it registered the me-too pesticides under 7 U.S.C. § 136a(c)(7)(A) when Syngenta had previously requested cancellation of its registrations, Syngenta's allegations parallel those made in paragraph 188. Although Syngenta has standing to pursue its allegations in paragraphs 189 and 193 that relate to Syngenta's request for voluntary cancellation and EPA's delay in cancellation in order to analyze and register me-too pesticides, see supra pp. 27-29, these allegations are duplicative of those in paragraph 188 of Count II.

The allegations in paragraph 190 center around EPA's permitting the Metolachlor Registrants to submit required data "years after the deadlines imposed upon Syngenta for its registration of similar pesticides had passed." There is no support in the record that Syngenta suffered an injury in fact from EPA's permitting the Metolachlor Registrants to submit studies that remained data gaps for metolachlor years after the original deadline for then-metolachlor-registrants to submit the data. None of Syngenta's rights were violated by such action.

Furthermore, Syngenta has no prudential standing to pursue this claim. Syngenta is not regulated by EPA's permitting the Metolachlor Registrants to submit data under new deadlines. Nor are Syngenta's interests — competitive interests if there were such an injury in fact — protected by the statutory provision at issue. 7 U.S.C. § 136a(c)(7)(A) permits EPA to register a pesticide even if an applicant is unable to submit certain data, as long as EPA "will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered." Congress enacted legislation in 1978 authorizing EPA to issue conditional registrations, something EPA had never before had the authority to do. 47 Fed. Reg. 57624, 57625 (Dec. 27, 1982). Prior to the 1978 amendment to FIFRA, EPA believed it was required to deny registrations of new products, even if they contained old ingredients, until all testing of the pesticide was complete and results reviewed. Id. EPA, Congress, and the pesticide industry were concerned about the difficulty this posed for applicants seeking to enter the market with products essentially the same as already-registered products. Id. Therefore, conditional registration serves to "eliminate barriers to registration and market entry" and "provide a needed transition phase between the case-by-case approach [of the past] and the new registration standards process." Id. Syngenta's commercial interests as the registrant of an already-registered pesticide are not protected by EPA's discretionary authority to grant conditional registrations and set deadlines for data submission. As a result, Syngenta does not have



standing to pursue its claim in paragraph 190.

Nor does Syngenta have standing to pursue its claims in paragraphs 191 and 192. In paragraph 191, Syngenta alleges EPA acted arbitrarily and capriciously in determining that the me-too registrations would not significantly increase the risk of unreasonable adverse effects on the environment. In paragraph 192, Syngenta asserts that EPA failed to conduct an incremental risk assessment. EPA has discretion to conditionally register pesticides if EPA determines doing so “would not significantly increase the risk of any unreasonable adverse effect on the environment.” 7 U.S.C. § 136a(c)(7)(A). “[C]entral” to conditional registration is the incremental risk assessment. 47 Fed. Reg. 57624, 57626. However, the record does not support an injury in fact — a concrete, particularized, and actual injury — to Syngenta. Instead, the only injury is likely a perceived harm to the environment due to “unnecessary additional loading on the environment of millions of pounds of pesticide each year.” SASC p. 49, ¶ 164. This “generally available grievance about government — claiming only harm to [Syngenta’s] and every citizen’s interest in proper application of the . . . laws . . . does not state an Article III case or controversy.” Lujan, 504 U.S. at 573-74.

In sum, of the allegations in Count II, Syngenta has standing to pursue as a stand-alone claim that in paragraph 188.

### **3. Count III**

In Count III of SASC, Syngenta alleges EPA’s actions violate the Equal

Protection Clause of the Fifth Amendment of the United States Constitution.

Despite this claim, Syngenta is unable to show injury from EPA's alleged actions.

An injury in fact suffered from an equal protection violation is the "inability to compete 'on an equal footing.'" Farmer v. Ramsay, No. 01-2039, 2002 WL 1766615 \*1, \*5 (4th Cir. 2002) (quoting N.E. Fla. Chapter, Associated Gen. Contractors of Am. v. City of Jacksonville, 508 U.S. 656, 666 (1993)) (both cases involving race-based equal protection violation allegations).

In the February 2008 hearing before Magistrate Judge Eliason involving the compelling of discovery, Judge Eliason inquired of Syngenta in the context of its equal protection claim, "[I]s your claim that you're injured because your competitors gained an advantage and that's where your injury is?" Hr'g Tr. 18:20-23 [Dock. 304]. Syngenta's response was "We're not alleging an injury to Syngenta, we're challenging the legality of EPA's decision to grant registrations improperly to our competitors." Id. at 18:24-19:2. Judge Eliason attempted to clarify Syngenta's equal protection claim and associated injury when he said,

[I]f I thought that part of your equal protection claim was going to start saying that, and this benefited [sic] our competitors and that's where the injury is, then, I'm going to grant the motion to compel because you're bringing competition in as a factor for the court to weigh in determining whether EPA somehow applied the incorrect standard.

Id. at 19:3-11. Syngenta responded, "That is really not where we have gone." Id. at 19:19-18. Again Judge Eliason responded,

If you're going to tell the Court, and by the way, we were treated

differently and we have suffered a competitive injury, that is, our competitors profited from this, and, therefore, that's why we wanted you to allow us to pursue the equal protection claim, . . . then, I think that the request with respect to your motives in wanting to cancel may well come into play. But if we're not going to get into that, and it may well cut out your equal protection claim entirely because you don't have any injury.

Id. at 19:15-20:2. Syngenta replied, "We're not seeking any relief for injury to Syngenta. . . . We do think that the biggest benefit from pursuing this lawsuit is to ensure that there is consistency, certainty and transparency in how EPA applied the standards that Congress laid out in the statute." Id. at 20:28-19.

Not only did Syngenta disavow injury in the hearing before Judge Eliason as it relates to its equal protection claim, but since that time Syngenta has not proffered evidence of any such injury. Instead, Syngenta asserts injury for all of its claims solely on the alleged exclusive use rights violation. See, e.g., Syngenta's Opp. MANA's Mtn. Dismiss 6. However, if a violation of its exclusive use rights occurred, such injury is insufficient to support Syngenta's equal protection violation claim. In pursuing its equal protection claim, Syngenta has focused on EPA's refusal to cancel Syngenta's technical metolachlor registration while me-too applications were pending, not on EPA's alleged violation of Syngenta's exclusive use rights. Consequently, it is determined that, having suffered no injury related to its equal protection claim, Syngenta does not have standing to pursue Count III.

## **D. Unclean Hands**

### **1. Applicability of the Doctrine**

The doctrine of unclean hands “closes the door of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant.” Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945). The “misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character.” Id. at 815. Instead, “[a]ny willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim.” Id. Further, if a party’s hands are unclean, a court has discretion in applying the doctrine. Id. at 814. Thus, a court may bar all recovery for the party or a court may bar recovery for only the claims tainted by the unclean hands. Smith v. Cessna Aircraft Co., 124 F.R.D. 103, 107 (D.Md. 1989) (citing Pennsylvania, Illinois, New Jersey cases for this proposition).

MANA claims the doctrine of unclean hands bars any equitable relief this Court could grant Syngenta. However, neither the internal memoranda nor any other of Syngenta’s actions supports the application of the doctrine of unclean hands. Instead, the documents MANA cites reflect appropriate business decisions discussed by Syngenta, a participant in a competitive market. Therefore, it is determined that the doctrine of unclean hands is inapplicable.

## 2. MANA's Motion to Unseal

After filing its Motion to Dismiss for Lack of Subject Matter Jurisdiction and Memorandum in Support, MANA filed a motion to unseal those documents, along with accompanying exhibits. MANA filed its motion to dismiss and memorandum in support of its motion under seal because, not only did it attach as exhibits two confidential internal memoranda of Syngenta, but it referred specifically to those documents in its memorandum. The two internal Syngenta memoranda were submitted to MANA during discovery limited to MANA's unclean hands defense. These discovery documents were governed by a Second Amended Protective Order Governing Confidentiality to which the parties agreed<sup>16</sup> and the Court entered on March 28, 2008. By its terms, the Protective Order governed "discovery and the pre-trial stage of this litigation[,]" but did "not address the introduction of any evidence at the final trial of this matter or the reference to any information in open court at the final trial of this matter." Moreover, the Court entered the Protective Order pursuant to Federal Rule of Civil Procedure 26(c) which provides for the entry of an order for good cause protecting a party or person during discovery. "Once the documents [sealed under the Protective Order governing discovery] are made part of a dispositive motion, they lose their status of being raw fruits of

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<sup>16</sup>At the time of the agreement, Agan Chemical Manufacturers, Ltd. ("Agan") was awaiting decision from the Court on its motion to dismiss for insufficient service of process. See Dock. 277. Therefore, Agan was not a party to the Second Amended Protective Order Governing Confidentiality.

discovery.” Rushford, 846 F.2d 249, 252 (internal citations omitted); see also id. (“[Pre-trial] discovery, which is ordinarily conducted in private, stands on a wholly different footing than does a motion filed by a party seeking action by the court.”).

Although the Fourth Circuit has recognized that there may be times when discovery documents should remain sealed even after their submission as part of a dispositive motion, id. at 253, Syngenta has not made a sufficient showing that its interests override the public right of access under either the common law or First Amendment doctrines of public access.<sup>17</sup> While Syngenta argues in opposition to MANA’s motion to unseal that the confidential documents “contain sensitive and valuable confidential business information regarding Syngenta’s internal decision-making and strategy regarding business, regulatory, and legal analysis and decisions,” the Court does not find that the confidential memoranda reveal information damaging to Syngenta. Instead, the documents, now over a decade old, contain innocuous business plans that, not only fail to support the unclean hands doctrine, but also do not reveal strategies unique to Syngenta. The documents certainly provide no information which would benefit a competitor nor otherwise harm Syngenta. Therefore, it is determined that MANA’s motion to

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<sup>17</sup>MANA filed its motion to unseal on April 28, 2008, and Syngenta filed its opposition to the motion on May 22, 2008 to which MANA replied on June 6, 2008. See Docks. 342, 359, 360. The public and other interested parties have had ample notice of MANA’s and Syngenta’s positions and have not commented on the issue. See Va. Dep’t of State Police v. Washington Post, 386 F.3d 567, 576 (4th Cir. 2004) (describing the procedure the district court must follow in determining whether or not to seal documents).

dismiss for lack of subject matter jurisdiction, Dock. 317, and memorandum in support of its motion along with the attached exhibits, Dock. 318, should be unsealed.

#### **IV. Summary Judgment Motions - Arbitrary and Capricious Agency Action**

In this case, the Court is reviewing the decision of EPA, the finder of fact, to determine summary judgment. This is different than determining summary judgment in an original district court proceeding. Occidental Eng'g Co. v. INS, 753 F.2d 766, 770 (9th Cir. 1985). Here, "summary judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." Id. "[T]he focal point for judicial review should be the administrative record already in existence' . . . [that] the agency presents to the reviewing court." Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 743-44 (1985) (quoting Camp v. Pitts, 411 U.S. 138, 142 (1973) and citing Citizens to Pres. Overton Park v. Volpe, 401 U.S. 402 (1971)). This record need not be the product of a formal hearing, but may instead be compiled by the agency during the course of its informal action. Id. at 744.

When reviewing agency actions under the APA, a court will set aside agency actions or find them unlawful only when they are "found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). This narrow review is "highly deferential, with a presumption in favor of finding the agency action valid." Ohio Valley Envtl. Coal. v. Aracoma

Coal Co., 556 F.3d 177, 192 (4th Cir. 2009); see also Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994) (stating a court must give substantial deference to an agency's interpretation of its own regulations unless an "alternative reading is compelled by the regulation's plain language or by other indications of the [agency's] intent at the time of the regulation's promulgation") (internal citations omitted). This is especially true when "the regulation concerns 'a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" Thomas Jefferson Univ., 512 U.S. at 512 (quoting Pauley v. BethEnergy Mines, Inc., 501 U.S. 680, 697 (1991)). Nonetheless, the court must engage in a "searching and careful" inquiry that "educate[s] the court" so it may "understand enough about the problem confronting the agency to comprehend the meaning of the evidence relied upon and the evidence discarded; the questions addressed by the agency and those bypassed; the choices open to the agency and those made." Ohio Valley Envtl. Coal., 556 F.3d at 192-93 (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 34 (D.C.Cir. 1976)).

Agency action is arbitrary and capricious

if the agency has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.



Ohio River Valley Envtl. Coal., Inc. v. Kempthorne, 473 F.3d 94, 102 (4th Cir. 2006) (quoting Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). The agency needs to have examined the relevant data and provided an explanation of its determination that includes “a ‘rational connection between the facts found and the choice made.’” Ohio Valley Envtl. Coal., 556 F.3d at 192 (quoting Motor Vehicle Mfrs. Ass’n, 463 U.S. at 43 (1983) (internal citations omitted)). The agency must have provided the explanation at the time of its action, and neither the court nor the agency may do so on appeal. Inova Alexandria Hosp. v. Shalala, 244 F.3d 342, 350 (4th Cir. 2001).

#### **A. Count I**

Syngenta alleges that the studies it submitted in support of its s-metolachlor registration were exclusive use studies and EPA violated its exclusive use rights by permitting the Metolachlor Registrants to rely on two of those studies in support of their me-too registrations. While, for the following reasons, the Court finds the studies Syngenta submitted in support of its s-metolachlor registration to be exclusive use studies,<sup>18</sup> EPA did not violate Syngenta’s exclusive use rights. EPA

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<sup>18</sup>In his memorandum explaining EPA’s me-too registration of Cedar’s Technical Metolachlor, EPA’s Herbicide Branch Chief stated that Cedar’s me-too application did not rely on any data that Syngenta submitted for s-metolachlor. AR 211. “For this reason, [Herbicide Branch] did not need to determine whether the Syngenta S-Metolachlor studies are entitled to exclusive use treatment.” Id. However, in a footnote, the Chief declares that the studies would not be considered exclusive use studies because they were required to maintain in effect an existing registration. Id. Although agency determinations are due deference,

did not act arbitrarily and capriciously when registering the Metolachlor Registrants' me-too pesticides as its actions pertain to the allegations in Count I of the SASC. Thus, summary judgment in favor of EPA, Drexel, and Sipcam for Count I is appropriate.

Syngenta applied to register s-metolachlor under EPA's reduced risk initiative. AR 291. As part of its data in support of the registration, Syngenta used bridging data from studies submitted for metolachlor's registration. Id.; AR 11. On March 14, 1997, EPA conditionally registered s-metolachlor with an expiration date of February 14, 1998. AR 211 att. After registering s-metolachlor, EPA continued to evaluate the sufficiency of bridging data Syngenta used to support s-metolachlor. AR 11; see also AR 14 (clarifying EPA's April 11, 1997 review of data submitted for s-metolachlor) and AR 17 (explaining that Syngenta received in May 1997 a review of the environmental fate studies it submitted in January 1996 as part of its s-metolachlor registration). When EPA agreed in its February 6, 1998 letter to Syngenta to remove s-metolachlor's registration expiration, it required the submission of studies that had been part of the communications between EPA and Syngenta. AR 15 (noting that Syngenta had already responded to data gaps for environmental fate studies such as field dissipation studies with terrestrial and turf studies but that its response was pending EPA review); AR 12

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this particular EPA determination is found only in a footnote to a sentence that acknowledged the Herbicide Branch itself did not determine whether Syngenta's studies were exclusive use studies.

(discussing the need for rat metabolism and side-by-side subchronic studies); AR 14 (clarifying the requirement for avian reproduction studies, fathead minnow life-cycle and early life stage study, daphnia 21-day flow-thru study, acute fish sheepshead minnow study, acute mysid shrimp study, and acute mollusk-*C.virginica* study). Although Syngenta refers to several required studies, including the fathead minnow life cycle and early life stage study, as “new data requirements” in its July 2, 1998 letter to EPA, these requirements were not new to the conversation between EPA and Syngenta that took place over the course of the prior year concerning data submission. See, e.g., AR 14. Instead, the studies required of Syngenta, in particular the fathead minnow life-cycle and early life stage study and the terrestrial field dissipation study, had been part of EPA’s review of the bridging data Syngenta submitted in support of s-metolachlor’s registration. Those studies and others would continue to be debated between EPA and Syngenta. See, e.g., AR 23 (detailing EFED’s completed review in late 1998 of ecological testing requirements for s-metolachlor).

Admittedly, EPA’s explicit requirement in its February 6, 1998 letter to Syngenta of the submission of particular studies, including the fathead minnow life-cycle and early life stage study and the terrestrial field dissipation study, comes after the March 14, 1997 conditional registration of s-metolachlor. However, this chronology does not necessarily mean that the studies Syngenta submitted as a result of the February 6, 1998 letter are defensive data. These studies were not

submitted as a result of EPA's determination that additional data was necessary to maintain in effect an existing registration, see 7 U.S.C. § 136a(c)(2)(B), such as the early 1990's Data Call-Ins EPA issued to all metolachlor registrants. Instead, detailed review of the communications between EPA and Syngenta reveal that the required studies became necessary after EPA determined bridging data used to register s-metolachlor was insufficient. The initial expedited review pursuant to the reduced risk initiative of s-metolachlor permitted EPA to register s-metolachlor according to 7 U.S.C. § 136a(c)(7)(C), which states, in relevant part

The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data [on certain conditions]. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

Syngenta's fathead minnow life-cycle and early life stage study and the terrestrial field dissipation study (1) pertained to a new active ingredient first registered after September 30, 1978, (2) were submitted in support of, or as a condition of approval of, the application resulting in the first registration of a product containing such new chemical, and (3) were not submitted to maintain an existing registration. See 40 C.F.R. § 152.83. Therefore, the studies are exclusive use studies for the ten-year period following the date of first registration. Id.

Although Syngenta's fathead minnow and terrestrial field dissipation studies were exclusive use studies, Syngenta's exclusive use rights were not violated

because EPA did not use Syngenta's studies when it registered the Metolachlor Registrants' me-too pesticides. EPA's EFED drafted a "note to file" in February 2002 stating "selected ecotoxicity data<sup>19</sup> for s-metolachlor were used to satisfy data requirements for metolachlor." AR 177. However, in March 2002, EPA's EFED drafted a "note to file - clarification" in which it explained that the question of whether certain ecotoxicity and environmental fate studies that Syngenta submitted for s-metolachlor could be used to assess ecotoxicity and fate of metolachlor was "posed from a scientific perspective." AR 197. "It was not [the EFED's] intent to give an opinion as to whether certain Syngenta ecotoxicty studies conducted on S-Metolachlor fulfilled any data requirements for Metolachlor." Id. In addition, the Herbicide Branch Chief stated in his memorandum explaining the registration of Cedar's me-too pesticide that Cedar's application did not rely on any data that Syngenta had submitted in support of s-metolachlor's registration. AR 211.

Moreover, neither the fathead minnow life-cycle and early life stage study nor the terrestrial field dissipation study were listed as data gaps in the RED for metolachlor. See AR 7 (listing 72-4A Early Life Stage Fish with a citation study number and 164-1 Terrestrial Field Dissipation with three citation study numbers). EPA required Syngenta to submit the studies for s-metolachlor, though, because s-

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<sup>19</sup>Ecotoxicity data includes the fathead minnow life-cycle and early life stage study. Syngenta's Br. Supp. Mtn. S.J. 11.

metolachlor was registered as a new active ingredient using bridging data for metolachlor. AR 211, att.; AR 291. In its review of sufficient data for bridging purposes, EPA determined the fathead minnow study performed for metolachlor was supplemental and could not be bridged. AR 14. EPA found discrepancies in the original and new metolachlor bridging data for the environmental fate studies, of which the terrestrial field dissipation is one. AR 17. Ultimately, EPA required Syngenta to submit both studies for s-metolachlor's registration. AR 15.

When EPA conditionally registered the Metolachlor Registrants' me-too metolachlor pesticides, EPA did not require the submission of the fathead minnow life-cycle and early life stage study or the terrestrial field dissipation study. This was not because, as Syngenta argues, EPA was relying on Syngenta's studies to satisfy those two requirements. Instead, as noted above, those two studies were not data gaps for metolachlor.<sup>20</sup> Consequently, they were not required in order to

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<sup>20</sup>In a memorandum drafted after its February 5, 1998 memorandum, EFED updated its review of the ecological effects data. AR 215. When explaining that EFED needed satisfactory chronic testing for fish and invertebrates with s-metolachlor, EFED stated "EFED presently has no valid chronic aquatic data for metolachlor or s-metolachlor. All studies with metolachlor (fish and invertebrate) were found to be invalid or supplemental." Id. EFED further states "no fully acceptable chronic data for either of the two chemicals" exists so "no true chronic risk potential for s-metolachlor can be predicted." Id. Syngenta argues that this evidences a data gap for metolachlor for the fish chronic aquatic data which includes the fathead minnow study. However, this EFED analysis is in the context of permitting Syngenta to use bridging data from metolachlor for s-metolachlor, a new active ingredient. In that context, EFED found the chronic fish study to be invalid or supplemental and not fully acceptable. This does not mean, however, that EPA would find the study necessary for a me-too metolachlor registration.

register the me-too metolachlor pesticides.

Since EPA was not relying on Syngenta's studies submitted in support of s-metolachlor when it registered the Metolachlor Registrants' me-too pesticides, EPA was not required to provide thirty days notice to Syngenta. Such notice is required before EPA registers a product containing an active ingredient for which a previously submitted study is eligible for exclusive use. 40 C.F.R. § 152.116(a). However, the Metolachlor Registrants' me-too applications and registrations did not rely on any of Syngenta's s-metolachlor studies. Therefore, Syngenta was not due thirty days notice.

In sum, although Syngenta's studies submitted in support of s-metolachlor were exclusive use studies, they were not used in support of the Metolachlor Registrants' me-too pesticide registrations. The administrative record is replete with evidence, see, e.g., supra pp. 42-46, that EPA examined the relevant facts as it determined what data were sufficient for Syngenta to bridge with s-metolachlor, what data were gaps for metolachlor, and ultimately what data were required of Syngenta and the Metolachlor Registrants. The record provides an explanation that reflects a rational connection between the facts found and the choice made. Therefore, not only did EPA not violate Syngenta's exclusive use rights under FIFRA, but it also did not act arbitrarily and capriciously. It is determined that EPA's motion for summary judgment and Drexel's motion for summary judgment, which Sipcam joins, for Count I be granted and that Syngenta's motion for

summary judgment for Count I be denied.

## **B. Count II**

Because Syngenta only has standing to pursue the claim in paragraph 188 — as reiterated in paragraphs 189 and 193 — of Count II, the Court’s review for summary judgment focuses only on Syngenta’s assertions concerning EPA’s delay in cancelling Syngenta’s technical metolachlor registration while EPA reviewed and ultimately registered the Metolachlor Registrants’ me-too pesticides. Although EPA admittedly delayed cancelling Syngenta’s technical metolachlor registration while the Metolachlor Registrants’ me-too applications were pending, EPA did not act arbitrarily and capriciously in doing so.

Syngenta resubmitted its request for voluntary cancellation of its technical metolachlor registration in September 1999. AR 293. 7 U.S.C. § 136d(f)(1)(A) provides that Syngenta may, at any time, request EPA to cancel its metolachlor registrations. The statute dictates that, upon receipt of cancellation request, EPA must publish in the Federal Register notice of such receipt for either a 30-day or 180-day period. 7 U.S.C. § 136d(f)(1)(B), (C). EPA published notice beginning in December 1999 for a 180-day period. AR 294. During the period for public comment, Cedar applied for a me-too technical metolachlor registration based on Syngenta’s technical metolachlor registration and submitted objections to the cancellation of Syngenta’s registration. AR 29; AR 297. Once the period for public comment ended in June 2000, EPA “may [have] approve[d] or den[ied]



[Syngenta's cancellation] request." 7 U.S.C. § 136d(f)(1)(D). But, the statute does not require that EPA act within any period of time, nor does the statute require EPA to approve the cancellation at all.

Not only does the statute not require cancellation, but EPA determined that delaying cancellation of Syngenta's technical metolachlor registration was consistent with FIFRA. In its communications with Syngenta, EPA noted that it "will continue to leave Syngenta's Technical Metolachlor registration in effect until EPA completes its review of all pending me-too applications to register metolachlor. [EPA] believe[s] this is consistent with the purpose of the procedures set forth in FIFRA § 6(f)." AR 303; see 7 U.S.C. 136d(f) (procedures for voluntary cancellation). Deference is given to EPA's interpretation of the purpose of the voluntary cancellation procedures. The statute's plain language does not demand a different reading. See Thomas Jefferson Univ., 512 U.S. at 512 (noting no deference afforded when plain language compels alternate reading). Instead, the statute involves a "complex and highly technical regulatory program" that "require[s] significant expertise and entails the exercise of judgment grounded in policy concerns." Id.

EPA expressed its opinion about the purpose of the voluntary cancellation procedures to Syngenta. In April 2002, EPA responded to Syngenta's inquiry concerning its cancellation request. AR 303. In its response, EPA stated that its earlier communications with Syngenta concerning Syngenta's cancellation request

were not intended “to commit the Agency to making decisions on Cedar’s me-too applications or Syngenta’s voluntary cancellation request by a date certain.” Id. Instead, EPA wrote that the intent of its earlier communication with Syngenta was “to ensure that Syngenta would continue to have the option of continued access to the Metolachlor market in the event Cedar’s application was granted, and that Syngenta would have notice about the Agency’s approach to its voluntary cancellation in the same time frame as any Agency action on the then-pending Cedar applications.” Id. Since EPA granted Cedar’s, Sipcam’s, and Drexel’s me-too metolachlor registrations in March and April 2002, EPA offered Syngenta the opportunity to withdraw its voluntary cancellation request in order to remain in the market. Id.; AR 304. However, if EPA did not receive a withdrawal request from Syngenta, EPA was prepared to cancel Syngenta’s technical metolachlor registration since “the purpose of the FIFRA § 6(f) procedures [had] been served” with the registrations of the me-too pesticides. AR 304. Syngenta did not submit a withdrawal request, and EPA cancelled Syngenta’s technical metolachlor registration in August 2002. Dock. 330, Ex. 3.

Affording discretion to EPA’s understanding of FIFRA and the purpose behind its procedures, the Court determines EPA’s actions in delaying the cancellation of Syngenta’s technical metolachlor registration were not arbitrary and capricious. Therefore, EPA’s motion for summary judgment and Sipcam’s motion for summary judgment, which Drexel joins, are granted as to Count II, and

Syngenta's motion for summary judgment as to Count II is denied.

### **C. Count III**

Even had the Court determined that Syngenta had standing to pursue its equal protection claim in Count III, summary judgment in favor of EPA, Drexel, and Sipcam would be mandated. Syngenta alleges in Count III that "EPA has taken actions, including its refusal to cancel Syngenta's registration of metolachlor, by which it has intentionally treated Syngenta differently from similarly situated persons regulated under FIFRA and thereby discriminated against Syngenta." Syngenta is unable to support its allegations.

In order to succeed on this claim, Syngenta "must first demonstrate that [it] has been treated differently from others with whom [it] is similarly situated and that the unequal treatment was the result of intentional or purposeful discrimination." Morrison v. Garraghty, 239 F.3d 648, 654 (4th Cir. 2001). If Syngenta were able to make this showing, the Court would then "determine whether the disparity in treatment can be justified under the requisite level of scrutiny." Id. Syngenta, however, is unable to overcome the first hurdle of demonstrating that EPA treated Syngenta differently from others similarly situated.

The class similarly situated to Syngenta would be pesticide manufacturers who sought voluntary cancellation of their registrations prior to the submission of

me-too applications.<sup>21</sup> The only similarly situated pesticide manufacturer is Sergeant's.<sup>22</sup> Sergeant's sought voluntary cancellation of products containing naled on September 28, 2001. EPA's Resp. Syngenta's 2nd Interrogs. & Reqs. 23 [Dock. 316, Att. 11]. During the thirty-day notice and comment period, Amvac submitted a me-too application based on Sergeant's naled products. Id. at 24. "Because EPA could not grant (under section 3(c)(7)(A) of FIFRA) Amvac's pending me-too application after canceling Sergeant's registrations, EPA delayed acting on Sergeant's cancellation request so that it would have time to evaluate whether the

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<sup>21</sup>Syngenta also argues EPA treated it differently than other pesticide registrants who failed to pay annual maintenance fees. Although Syngenta cites to the Federal Register announcing cancellation of hundreds of registrations for failure to pay maintenance fees with the exception of Syngenta's registration and to the deposition of John Jamula where he states "generally [EPA] cancel[s] the product" when a registrant indicates it is not going to pay the maintenance fee, Syngenta does not provide evidence that those registrations had pending me-too applications dependent upon the continuation of the registrations. See 66 Fed. Reg. 38675 (July 25, 2001) [Dock. 326, Ex. 2]; 67 Fed. Reg. 54114 (Sept. 6, 2000) [Dock. 337, Ex. 5]; Dep. J. Jamula 24:11-15 [Dock. 321, Ex. 8].

<sup>22</sup>The only other situation in which manufacturers sought voluntary cancellation when me-too applications were involved was not similar to Syngenta's situation. On June 30, 2003 Osmose submitted a request for voluntary cancellation of its product containing chromic acid and cupric oxide (ACC). EPA's Resp. Syngenta's 2nd Interrogs. & Reqs. 31. Six days prior, on June 24, 2003, Forest Products Research Laboratory submitted a me-too application based on Osmose's ACC registration. Id. Like in Syngenta's and Sergeant's situations, EPA did delay cancelling Osmose's registration in order to review the pending me-too application. Id. However, not only did Osmose request cancellation after the me-too application had been filed, but Osmose ultimately withdrew its cancellation request. Id. at 32. Nonetheless, while the me-too application was pending, EPA did not cancel Osmose's ACC registration. Id. Thus, EPA did not treat Osmose differently than Syngenta.

pending me-too applications met section 3(c)(7)(A) standard for registration.” Id. As of August 2004, EPA had not cancelled the naled registrations, nearly three years after Sergeant’s requested voluntary cancellation and approximately two and a half years after Amvac submitted its me-too application. Id. As of the date of EPA’s Response to Syngenta’s Second Set of Interrogatories and Requests for Documents,<sup>23</sup> EPA was unable to determine whether and, if so, when Sergeant’s products containing naled were cancelled. Id. Further, the me-too applications were still pending because of concerns of risk to humans. Id. There is no evidence EPA treated Syngenta differently than Sergeant’s by cancelling Sergeant’s registrations for products containing naled pending review of me-too applications. To the contrary, the evidence before the Court shows EPA treated Sergeant’s and Syngenta similarly - delaying their voluntary cancellation requests in order to review and perhaps ultimately register the me-too pesticide applications.

Because Syngenta cannot show that EPA treated it differently than others similarly situated, it is unable to support a claim for denial of equal protection rights.

## **VI. Conclusion**

For the reasons stated above, **IT IS HEREBY ORDERED** that Sipcam’s motion for summary judgment on Syngenta’s claim of arbitrary and capricious agency action in violation of the Administrative Procedure Act [Dock. 308], which Drexel

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<sup>23</sup>November 29, 2007.

joins, is **GRANTED**, that Drexel's motion for summary judgment on Syngenta's claim of EPA action in violation of the Equal Protection Clause and violation of FIFRA's exclusive use provisions [Dock. 312], which Sipcam joins, is **GRANTED**, that EPA's motion for summary judgment on all Counts [Dock. 316] is **GRANTED**, that MANA's motion to dismiss for lack of subject matter jurisdiction [Dock. 317], which Sipcam and Drexel join, is **GRANTED IN PART AND DENIED IN PART**, that Syngenta's motion for summary judgment on all Counts [Dock. 319] is **DENIED**, and that MANA's motion to unseal its motion to dismiss and memorandum in support of its motion to dismiss [Dock. 342] is **GRANTED**.

This, the 9<sup>th</sup> day of August, 2011.

/s/ N. Carlton Tilley, Jr.  
Senior United States District Judge